

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0087808	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Martin's Point Health Care - Brunswick	Street Address, City, State 114 Bath Rd, Brunswick, ME	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC1), the laboratory failed to follow the written procedure to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency documentation for 2023-2024 on 12/18/2024 revealed no review of TC1 or TC2 for his /her CLIA federal regulatory responsibilities. 2. Record review of the laboratory's Competency of Laboratory Personnel policy on 12/18/2024 revealed the following the policy did not contain information for evaluating the laboratory's Technical Consultants. 3. Staff interview with the TC1 on 12/18/2024 at 11:00am confirmed the above findings. 4. The laboratory performs 7,809 tests annually in the specialty of Microbiology, 11,000 tests annually in Diagnostic Immunology, 1,149,096 tests annually in Chemistry, and 328,290 tests annually in Hematology.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,</p>

and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and staff interview with Technical Consultant (TC1), it was determined that the reference ranges for Glucose, Hemoglobin, and Mean Corpuscular Hemoglobin Concentration on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's reference ranges on 12/18/2024 for patient #1 with the laboratory's procedures for Chemistry and Hematology revealed the following: a. Final report: Glucose 70-140 mg/dL b. Policy: 74-106 mg/dL c. Final report: Hemoglobin 27-34 g/dL d. Policy: 27-33 g/dL e. Final report: Mean Corpuscular Hemoglobin Concentration 13.7-16.7 g/dL f. Policy 13-17 g/dL 2. Staff interview with the TC1 on 12/18/2024 at 11:00am confirmed the reference ranges did not correlate with the reference range on the final patient test report. 3. The laboratory performs 1,149,096 tests annually in the specialty of Chemistry and 328,290 tests annually in the specialty of Hematology.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of documentation and staff interview the laboratory director (LD) failed to specify, in writing, the responsibilities and duties of each Technical Consultant (TC1), and the Clinical Consultant (CC). Findings include: 1. Record review of the laboratory manual on 12/18/2024 revealed that (TC1, CC) responsibilities were not specified in writing as per federal regulatory requirements. 2. Interview with the (LD) on 12/18/2024 at 10:00am confirmed the above findings. 3. The laboratory performs 7,809 tests annually in the specialty of Microbiology, 11,000 tests annually in Diagnostic Immunology, 1,149,096 tests annually in Chemistry, and 328,290 tests annually in Hematology.